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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/669,203	09/23/2003	Michael P. Wallace	03-247 (US01)	2638

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EXAMINER	
ROANE, AARON F	

ART UNIT	PAPER NUMBER
3739	

MAIL DATE	DELIVERY MODE
07/25/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/669,203	WALLACE, MICHAEL P.	
	Examiner	Art Unit	
	Aaron Roane	3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 May 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,6-14,16,18,19,25,26 and 37-42* is/are pending in the application.

4a) Of the above claim(s) *4,9,14,16 and 26* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,6-8,10-13,18,19,25 and 37-42* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *07 May 2007* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *5/7/2007*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Drawings

The drawings were received on 5/7/2007. These drawings are acceptable.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on 5/7/2007 was filed after the mailing date of the first office action on 1/4/2007. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement has been considered by the examiner.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-3, 6, 8, 10-13, 37 and 39-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ken et al. (USPN 5,853,418) in view Geremia et al. (USPN 5,108,407) and in further view of Wallace et al. (USPN 6,280,457).

Regarding claims 1, 6, 10, 11, 18, 19, 25, 37 and 39-42 Ken et al. disclose a vaso-occlusive device for treating a site within a patient's vasculature, the device comprising a helically wound coil (coiled formed by 102 and its analogous counterparts in the other embodiments) forming a lumen and formed of platinum (see col. 4, lines 47-60), a filament/heating member (first material) (108, 208 and 214 and their analogous counterparts in the other embodiments) disposed in the lumen, the heating member at least partially comprising a first highly resistive, ferrous material (contains iron), the first material that is embedded within the device and which may be heated by application of a source of energy external to a patient's body after the device is implanted at a treatment site in the patient's body, see col. 1-9, particularly col. 4, line 6 through col. 5, line 10 and figures 1A-11D. Ken et al. fail to disclose a bioactive agent that is activated or released when the device is heated. Ken et al. disclose a number of detachment methods for releasing the coil, see col. 1, line 49 through col. 2, line 63 and figures 3A-4C and 10. Geremia et al. disclose a vaso-occlusive coil device and teach an alternate method of detaching the coil from the device by heating and braking a second material in the form of an adhesive bond between the coil itself and the rest of the device, see abstract, col. 4, lines 14 col. 5, line 15 and figures 1-9. Wallace et al. also disclose a vaso-occlusive coil device and teach that "the polymeric fiber covering the device are used as a carrier for

bioactive molecules. Non-limiting examples of bioactive materials which increase cell attachment and/or thrombogenicity include both natural and synthetic compounds, e.g., collagen, fibrinogen, vitronectin, other plasma proteins, growth factors (e.g., vascular endothelial growth factor, "vEGF"), synthetic peptides of these and other proteins having attached RGD (arginine-glycine-aspartic acid) residues, generally at one or both termini. In addition, polynucleotide sequences encoding peptides (e.g., genes) involved in wound healing or promoting cellular attachment may also be used, see col. 12, lines 3-14. It should be noted the combination of Ken et al., Geremia et al. and Wallace et al. provides a coil that has a polymer/bioactive agent coating that is detached from the rest of the device by heating. Therefore at the time of the invention it would have been obvious to one of ordinary skill in the art to modify the invention of Ken et al., as taught by Geremia et al., to detach the coil from the device by heating and braking an adhesive bond between the coil itself and the rest of the device as an alternate detaching method, and as further taught by Wallace et al., to provide the coil with a polymeric coating having a bioactive agent in order to improve the vaso-occlusion treatment.

Regarding claims 2, 3, 12 and 13, Ken et al. in view Geremia et al. and in further view of Wallace et al. disclose the claimed invention, see Ken et al., col. 5, line 64 through col. 6, line 62 and figures 1A-2C.

Regarding claims 8 and 29, Ken et al. in view of Geremia et al. and in further view of Wallace et al. disclose the claimed invention. It can be clearly seen that (108 and all

analogous counterparts in other embodiments) of Ken et al. is embedded in the element, see figures 1A-10.

Regarding claim 30, Ken et al. in view of Geremia et al. and in further view of Wallace et al. disclose the claimed invention.

Regarding claim 34, Ken et al. disclose the claimed invention, see col. 1-9, particularly col. 4, line 6 through col. 5, line 10 and figures 1A-11D.

Claims 18, 19 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ken et al. (USPN 5,853,418) in view Geremia et al. (USPN 5,108,407) and in further view of Wallace et al. (USPN 6,280,457) and still in further view of Lee et al. (USPN 6,059,815).

Regarding claims, 18, 19 and 25 Ken et al. disclose a vaso-occlusive device for treating a site within a patient's vasculature, the device comprising a helically wound coil (coiled formed by 102 and its analogous counterparts in the other embodiments) forming a lumen and formed of platinum (see col. 4, lines 47-60), a filament/heating member (first material) (108, 208 and 214 and their analogous counterparts in the other embodiments) disposed in the lumen, the heating member at least partially comprising a first highly resistive, ferrous material (contains iron), the first material that is embedded within the device and which may be heated by application of a source of energy external to a patient's body after the device is implanted at a treatment site in the patient's body, see

col. 1-9, particularly col. 4, line 6 through col. 5, line 10 and figures 1A-11D. Ken et al. fail to disclose a bioactive agent that is activated or released when the device is heated by application of a magnetic field. Ken et al. disclose a number of detachment methods for releasing the coil, see col. 1, line 49 through col. 2, line 63 and figures 3A-4C and 10. Geremia et al. disclose a vaso-occlusive coil device and teach an alternate method of detaching the coil from the device by heating and braking a second material in the form of an adhesive bond between the coil itself and the rest of the device, see abstract, col. 4, lines 14 col. 5, line 15 and figures 1-9. Wallace et al. also disclose a vaso-occlusive coil device and teach that "the polymeric fiber covering the device are used as a carrier for bioactive molecules. Non-limiting examples of bioactive materials which increase cell attachment and/or thrombogenicity include both natural and synthetic compounds, e.g., collagen, fibrinogen, vitronectin, other plasma proteins, growth factors (e.g., vascular endothelial growth factor, "vEGF"), synthetic peptides of these and other proteins having attached RGD (arginine-glycine-aspartic acid) residues, generally at one or both termini. In addition, polynucleotide sequences encoding peptides (e.g., genes) involved in wound healing or promoting cellular attachment may also be used, see col. 12, lines 3-14. Finally, Lee et al. disclose an aneurysm occlusion device and teach the alternate/equivalence of laser, RF and magnetic inductive heating for heat release mechanisms, see col. 6, line 33 through col. 7, line 62. It should be noted the combination of Ken et al., Geremia et al. and Wallace et al. provides a coil that has a polymer/bioactive agent coating that is detached from the rest of the device by heating via a magnetic field. Therefore at the time of the invention it would have been obvious to

one of ordinary skill in the art to modify the invention of Ken et al., as taught by Geremia et al., to detach the coil from the device by heating and braking an adhesive bond between the coil itself and the rest of the device as an alternate detaching method, and as further taught by Wallace et al., to provide the coil with a polymeric coating having a bioactive agent in order to improve the vaso-occlusion treatment, and as still further taught by Lee et al., to use laser, RF and magnetic field as alternate/equivalents for heat releasing the coil.

Claims 7 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ken et al. (USPN 5,853,418) in view Geremia et al. (USPN 5,108,407) and in further view of Wallace et al. (USPN 6,280,457) as applied to claims 1 and 37 above, and further in view of Lee et al. (USPN 6,059,815).

Regarding claims 7 and 38, Ken et al. in view Geremia et al. and in further view of Wallace et al. disclose the claimed invention except for explicitly reciting the external energy source comprising magnetic resonance. Lee et al. disclose an aneurysm occlusion device and teach the alternate/equivalence of laser, RF and magnetic inductive heating for heat release mechanisms, see col. 6, line 33 through col. 7, line 62. Therefore at the time of the invention it would have been obvious to one of ordinary skill in the art to modify the invention of Ken et al. in view of Geremia et al. in further view of Wallace et al., and as still further taught by Lee et al., to use laser, RF and magnetic field as alternate/equivalents for heat releasing the coil.

Response to Arguments

Applicant's arguments filed 5/7/2007 have been fully considered but they are not persuasive. The examiner will address each argument/remark in turn.

Applicant asserts on page 13 last paragraph:

> *Under 35 U.S.C. §103(a), to establish a prima facie case of obviousness of a claim, all of the claim limitations must be taught or suggested, and all words in a claim must be considered in judging the patentability of that claim. In addition, there must be some suggestion or motivation to modify the primary references (in this case, Ken), and a reasonable expectation of success. The mere fact that Ken can be modified does not render the resultant modification obvious to do, unless the reference or some other source (of which none has been presented by the Examiner) also suggests the desirability of making the modification. MPEP § 2146.*

The examiner respectfully disagrees as the test of obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. In re Keller, 642 F. 2d 413, 425, 208 USPQ 871, 881 (CCPA 1981). In this regard, a conclusion of obviousness may be based on common knowledge and common

sense of the person of ordinary skill in the art without any specific hint or suggestion in a particular reference. In re Bozek, 416 F .2d 1385, 1390, 163 USPQ 545, 549 (CCPA 1969).

Additionally, regarding the arguments/remarks made on page 14 through page 15, 2nd paragraph, the examiner has interpreted the claim very broadly to include a coil comprising bioactive material that is released when heat since the coil is released when heated. If Applicant wishes to overcome this interpretation (and hence rejection), Applicant should provide some claim language which precludes this interpretation and make sure such language is supported by the specification. Although operational characteristics of an apparatus may be apparent from the specification, we will not read such characteristics into the claims when they cannot be fairly connected to the structure recited in the claims. See In re Self, 671 F.2d 1344, 1348, 213 USPQ 1, 5 (CCPA 1982).

Next, on page 16, 2nd paragraph, Applicant refutes Ken et al. by stating:

> *However, there is no mention or suggestion in Ken that such "modest amounts of iron" in the stretch-resisting filament are provided in adequate concentration to cause the stretch-resisting filament to act as a heating member if exposed to an external energy source (e.g., MR) when the coil is implanted at a treatment site. Nor is there any mention in Ken that the "optional" modest amounts of iron would be embedded in the filament versus applied as a coating, or otherwise. And, in particular, there is no mention in Ken that the coil itself contains, (or may optionally contain), any amount of iron, despite a very" detailed description of what materials the coils are made from (Col. 4, lines 47-60).*

It should be pointed out that the claim language recites "a filament at least partially positioned in the lumen, the filament comprising a highly resistive material" from claim 18, "the highly conductive material comprising platinum, the highly resistive material comprising ferrous material" from claim 19 and "the ferrous material is embedded in the filament" from claim 25. The prior art meets the claimed subject matter.

This action is made FINAL.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aaron Roane whose telephone number is (571) 272-4771. The examiner can normally be reached on Monday-Thursday 7AM-6PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Aaron Roane A.R.
July 20, 2007

Roy D. Gibson
ROY D. GIBSON
PRIMARY EXAMINER